

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
LIPIDURE REWETTING DROPS**

1. Submitter Information

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2. Device Name

Device Trade Name: Lipidure Rewetting Drops

Device Common Name: Rigid Gas Permeable In-Eye Contact Lens
Solution (Lubricating and/or Rewetting Drops)

Device Classification Name: Rigid Gas Permeable Contact Lens Care
Product

3. Predicate Device

Currently marketed Boston® Rewetting Drops, approved under PMA P820070, was selected as the predicate device. This product was selected because the formulation is similar and the indications for use are identical to the device proposed in this submission.

4. Description of the Device

Lipidure Rewetting Drops is a sterile, aqueous, buffered, isotonic solution containing PMB-82 as a wetting agent, preserved with chlorhexidine gluconate 0.0033% and edetate disodium 0.058% as a chelating agent, sodium chloride as a tonicity agent, sodium phosphate monobasic and dibasic as buffers, sodium hydroxide and hydrochloric acid as pH adjustors and Sterile Water for Injection.

Lipidure Rewetting Drops is a clear, colorless solution supplied sterile in plastic bottles with controlled dropper tips and labeled with lot number and expiration date.

5. Indications for Use

Lipidure Rewetting Drops are indicated for use directly in the eye to lubricate and rewet fluoro silicone acrylate (FSA) and silicone acrylate (SA) rigid gas permeable (RGP) contact lenses.

6. Description of Safety and Substantial Equivalence

A series of preclinical tests were conducted to demonstrate the safety and effectiveness of Lipidure Rewetting Drops. A summary of the results of these tests are presented below.

Shelf Life Testing:

Expiration dating will be established based on the Shelf-life Protocol in accordance with the Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.

Toxicology:

Systemic Injection Test

Acute toxicity of Lipidure Rewetting Drops was evaluated using albino Swiss mice in accordance with the USP Systemic Injection Test. The test article did not show a significantly greater biological reaction than the control.

Primary Ocular Irritation Test

Primary ocular irritation of Lipidure Rewetting Drops was evaluated using albino rabbits (New Zealand White) in accordance with the USP Eye Irritation Test. The test article was considered to be a non-irritant.

Cytotoxicity Test

The cytotoxicity of Lipidure Rewetting Drops was evaluated using L-929 cells in accordance with the USP Agar Diffusion Test. The test article did not cause pronounced cytotoxicity. The test article was considered to be non-cytotoxic.

Skin Sensitization Kligman Maximization

The allergenic potential or sensitizing capacity of Lipidure Rewetting Drops was evaluated in guinea pigs utilizing the Kligman Maximization Test. The test article did not exhibit a significant sensitization rate.

3 Week Ocular Safety in Rabbits

The potential of Lipidure Rewetting Drops to produce an irritating effect on ocular tissue was evaluated in New Zealand White Rabbits. The test article (Lipidure Rewetting Drops) was compared to the control article (Boston® Rewetting Drops) with the use of Boston IV® and Fluoroperm® lenses. Lenses were worn on a daily wear schedule and potential ocular irritation was evaluated after sustained use over a 21 day period. Under the conditions of this study, the test article showed no significantly great biological reactions in comparison with the control article.

Microbiology:

Sterility Testing

USP sterility testing of Lipidure Rewetting Drops has been conducted and no growth was observed in the recovery media during the 14 day incubation period.

Preservative Efficacy Testing

A prototype formulation of Lipidure Rewetting Drops, which was formulated with only 80% of the Chlorhexidine Gluconate (CHG) label claim, was evaluated for preservative efficacy. The solution was found to meet the requirements of the Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.

Solution Compatibility Testing

A study was conducted to determine the compatibility of Lipidure Rewetting Drops with various currently marketed RGP contact lens solutions. The solution mixtures did not produce any unusual property trends or results, with the exception of Boston Advance Cleaner. The Boston Advance Cleaner contains a high salt concentration to preserve the product and suspend the cleaning abrasive. Therefore, it was not unexpected that the mixture would separate when diluted with the isotonic Lipidure Rewetting Drops.

Lens Compatibility Testing

A study was conducted to determine the compatibility of Lipidure Rewetting Drops with silicone acrylate and fluorosilicone acrylate rigid gas permeable contact lenses. Lens properties were evaluated prior to and following 30 cycles of cleaning and soaking in RGP solutions and soaking in Lipidure Rewetting Drops. Lipidure Rewetting Drops did not have any marked effect on the properties of the lenses.

Clinical:

The purpose of this study was to demonstrate that Lipidure Rewetting Drops are substantially equivalent in safety and efficacy to the currently marketed Boston® Rewetting Drops. This 3 month, open label, prospective, controlled clinical study was designed in accordance with the Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.

A total of 148 eyes (74 subjects) were enrolled in the study by 5 investigators. Of the 148 eyes enrolled, 144 eyes (72 subjects) completed the 3 month study period. Approximately two-thirds of the subjects used the test solution (Lipidure Rewetting Drops) and one-third used the control solution (Boston® Rewetting Drops).

The data from the study were evaluated using summary statistics. Analysis of the safety and efficacy data collected during this study showed no significant differences between the test and control groups. The results of this study support the substantial equivalence of Lipidure Rewetting Drops to Boston® Rewetting Drops.

7. Substantial Equivalence

Lipidure Rewetting Drops are substantially equivalent in terms of action, indications for use, safety and effectiveness to the predicate device, currently marketed Boston Rewetting Drops approved under PMA P820070. Any differences between the new device and its predicate does not effect the use of this product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2000

Ms. Ann M. Kurowski
Consultant
Foresight Regulatory Strategies
269A Ballardvale Street
Wilmington, MA 01887

Re: K000975
Trade Name: Lipidure Reweting Drops
Regulatory Class: II
Product Code: MRC
Dated: August 14, 2000
Received: August 15, 2000

Dear Ms. Kurowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

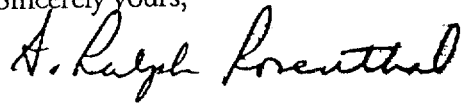
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive style with a large, stylized "A" and "R".

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000975

Device Name: Lipidure Rewetting Drops

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)

Division of Ophthalmic Devices

(Optional Format 3-10-98)

510(k) Number K000975